CLINICAL PHARMACOLOGY & BIOPHARMACEUTICS REVIEW

NDA:	22-115 (Sn-0024)
Brand Name:	Lamictal® XR
Generic Name:	Lamotrigine
Sponsor:	GlaxoSmithKline
Type of Dosage Form:	Extended-Release Oral Tablets
Strengths:	25 mg, 50 mg, 100 mg, 200 mg, and 300 mg
Indications:	Monotherapy for partial onset seizures (in patients 13 years of age and older)
OCP Reviewer:	Ta-Chen Wu, Ph.D.
OCP Team Leader:	Angela Yuxin Men, M.D., Ph.D.
OCP Division:	DCP-1 HFD-860
OND Division:	Neurology Drug Products HFD-120
Submission Date:	March 31, 2010
Type of Submission:	Prior Approval Efficacy Supplement

BACKGROUND:

The Sponsor is seeking the approval for Lamictal® XR™ (lamotrigine) Extended-Release Tablets for conversion to monotherapy in patients ≥13 years of age with partial seizures who are receiving therapy with a single antiepileptic drug (AED).

A pivotal clinical study (LAM30055) was conducted in subjects 13 years of age and older with partial seizures to support the efficacy of LAMICTAL XR, compared to the historical control, for this indication. Study LAM30055 was a 59-week, double-blind, randomized, historic control study. Eligible patients were randomized (1:1) to receive either 250 or 300 mg/day of Lamicatal XR. The double-blind treatment phase consisted of a 10~11-week Conversion Phase and a 12-week Maintenance (monotherapy) Phase. The LAMICTAL XR dose was escalated to the target dose, followed by the withdrawal of the background AED. The data for the historic control were pulled from 8 "conversion to monotherapy" studies which used a low dose of an approved AED (pseudoplacebo) as the comparator.

(b) (4)

CONCLUSION:

Office of Clinical Pharmacology has reviewed the proposed labeling for the Lamictal® XR™ and provided input on dosage adjustment and revision labeling languages. The agreement on the labeling recommendations was reached at the teleconference with the Sponsor on April 22, 2011. The final label will be available in the Approval Letter.

Ta-Chen Wu, Ph.D.
Reviewer, Neurology Drug Products, DCP-1, OCP

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/s/

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04/23/2011

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04/24/2011